

Remarks

Claims 1-8 are pending and currently subject to restriction. The Examiner has required restriction to one of twenty-four groups, identified as Groups I to XXIV in the Office Action dated June 20, 2007. The Examiner has indicated that restriction is required under PCT Rules 13.1 and 13.2 "since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art." Applicants provisionally elect, with traverse, Group I.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general concept (i.e., "requirement of unity of invention"). PCT Rule 13.2 states that unity of invention shall be fulfilled "when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". It further defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art".

The present invention is directed in part to a method of treating or inhibiting disorders associated with the activation of large conductance calcium activated potassium channels by administering a compound of Formula (I), which have a common utility as BK channel activators and as a whole have structural core similarity (corresponding to Groups I to XVIII). As the compounds of Formula I are similar in structure, such compounds are expected to have identical or similar chemical properties, modes of action, effects and reactive conditions. Therefore the claimed methods of treatment by administering a compound of Formula (I) of the present invention are not independent and distinct from each other. The invention is also directed to compounds of Formulae II, III, and IV, which each represent a subset of Formula I.

In light of this, claims 1-4 (corresponding to Groups I to XVIII), which define an inter-related compound structure set that does not lack unity under PCT Rule 13.1 and 13.2, but have a "significant structural element" qualifying as a "special technical feature" that defines a contribution over the prior art. Moreover, applicants respectfully maintain that the Examiner has not provided evidence to show why a serious search burden would be imposed upon examination of the claimed invention and/or why specific groups are unrelated because of different utilities, when the common technical feature of the claimed invention is a method of use directed to treating or inhibiting disorders associated with the activation of large conductance calcium activated potassium channels.

Applicants note that lack of unity under PCT rules 13.1 and 13.2 were not held during PCT examination in the corresponding PCT application to the present invention.

In accordance with 37 CFR § 1.475 (i.e., "Unity of Invention Before the International Searching Authority, the International Preliminary Examining Authority and During the National Stage):

(d) If multiple products, processes of manufacture or uses are claimed, **the first invention of the category first mentioned in the claims** of the application and the first recited invention of each

of the other categories related thereto **will be considered as the main invention in the claims**, see **PCT Article 17(3)(a)** and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

M.P.E.P Section 1850 III and PCT Gazette, Annex B Unity of Invention – Section IV defines combinations of categories of invention considered to have unity of invention. One such category where unity exists between two claims is defined as follows: if claimed compounds exhibit the claimed use or method of the invention, the interlinking or special technical feature is defined as the use or method of the invention (see attached PCT Gazette, Part 2 at pages 9478-9488, Exs. 1, 4 and 16, esp. Ex. 4 therein).

In accordance with 37 § CFR 1.475 (d) and MPEP Section 1850, the main invention of the present application would be the method of use defined by claim 1, the first mentioned claim in the application. In the present invention, unity of invention is present, because the special technical feature between the claims is treating or inhibiting disorders associated with the activation of large conductance calcium activated potassium channels, as compounds of Formula (I) and Formulae (II, III, and IV) (which represent a subset of compounds of Formula (I)) are capable of activating BK channels.

Applicants note that all twenty-four of the Examiner's Groups fall into one of three classes. Groups I to XVIII are classified in class 514. Groups XIX, XXII, XXIII, and XXIV are classified in class 548. And, Groups XX and XXI are classified in class 549. Applicants respectfully assert that the Examiner has failed to establish that a serious search burden would be imposed by examination of the groups within these three classes.

According to the Examiner's classification, the compounds of the invention wherein X is NR_a fall within class 548, and the compounds of the invention wherein X is O or S fall within class 549. Applicants respectfully suggest that examination the instant method of use claims (claims 1-4) and the remaining compound claims (claims 5-8) according to this distinction (X is NR_a, or X is O or S) would not impose a serious burden on the Examiner.

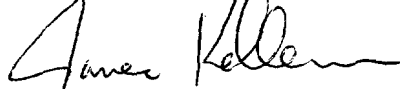
Applicants respectfully submit that the multiple restrictions in this case place a significant burden on Applicants. This case has been divided into 24 allegedly patentably distinct cases by the USPTO – with no showing that it would be an undue burden to search or examine the claimed subject matter. Accordingly, Applicants respectfully request that the Examiner reconsider the present restriction requirement.

Applicants reserve the right to file non-elected inventions as the subject of future applications, which may derive priority from the present application, without prejudice.

If any additional fees or charges are required authorization is hereby granted to charge any necessary fees to Deposit Account No. 19-2570 accordingly.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "James C. Kellerman". The signature is fluid and cursive, with the first name "James" written in a larger, more prominent script than the last name "Kellerman".

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